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FILED ENTERED	RECEIVED SERVED ON COUNSEL/PARTIES OF RECORD
MAY 27 2025	
CLERK US DISTRICT COURT DISTRICT OF NEVADA	
BY: <u>RMG</u>	DEPUTY

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA**

RAY L. FLORES II,

Plaintiff,

v.

ROBERT F. KENNEDY, JR.,
In his official Capacity as Secretary of the
Department of Health and Human Services,

Defendant.

Civil Action 2:25-cv-00916-JAD-NJK

EXHIBIT INDEX

- | | |
|-----------------------|---|
| Exhibit No. 1: | 1983 Childhood Immunization Schedule |
| Exhibit No. 2: | UNITED STATES 2025 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger |
| Exhibit No. 3: | 60-Day Demand to Secretary Kennedy |
| Exhibit No. 4: | U.S.P.S. Tracking Confirmation |
| Exhibit No. 5: | Complaint for Declaratory and Injunctive Relief |
| Exhibit No. 6: | Stipulation for Dismissal |
| Exhibit No. 7: | Letter from HHS dated June 22, 2018 Task Force Disbanded in 1998 |

EXHIBIT INDEX

EXHIBIT 1

1983 Childhood Immunization Schedule

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s) [†]	Comments
2 mo.	DTP-1, [§] OPV-1 [¶]	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR ^{††}	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr. ^{§§}	DTP-5, OPV-4	Preferably at or before school entry
14-16 yr	Td ^{¶¶}	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

[†]For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

[§]DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

[¶]OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

^{††}MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

^{§§}Up to the seventh birthday.

^{¶¶}Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

1983 childhood immunization schedule

EXHIBIT 2

UNITED STATES 2025

Recommended Child and Adolescent Immunization Schedule for ages 18
years or younger

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES
2025

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus
Vaccine	Abbreviation(s)	Trade name(s)
COVID-19 vaccine	1vCOV-mRNA	Comirnaty/Pfizer-BioNTech COVID-19 Vaccine
	1vCOV-aPS	Spikevax/Moderna COVID-19 Vaccine Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
<i>Haemophilus influenzae</i> type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vagta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	cclIV3	Flucelvax
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prenvax 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1	Rotarix
	RV5	RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines (use combination vaccines instead of separate injections when appropriate)		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and <i>Haemophilus influenzae</i> type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, <i>Haemophilus influenzae</i> type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

11/21/2024

How to use the child and adolescent immunization schedule

- 1** Determine recommended vaccine by age (Table 1)
- 2** Determine recommended interval for catch-up vaccination (Table 2)
- 3** Assess need for additional recommended vaccines by medical condition or other indication (Table 3)
- 4** Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)
- 5** Review contraindications and precautions for vaccine types (Appendix)
- 6** Review new or updated ACIP guidance (Addendum)

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/acip/index.html) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.



Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- General Best Practice Guidelines for Immunization (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/



U.S. CENTERS FOR DISEASE
CONTROL AND PREVENTION

PAGE 1 of 2



CS310020-E

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

PAGE 2 of 2

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars. To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs			
Respiratory syncytial virus (RSV-mAb [Nirsevimab])	1 dose depending on maternal RSV vaccination status (See Notes)					1 dose (8 through 19 months), See Notes														
Hepatitis B (HepB)	1st dose	← 2nd dose →			← 3rd dose →															
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes															
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose		← 4th dose →				5th dose									
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		← 3rd or 4th dose (See Notes) →													
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose		← 4th dose →													
Inactivated poliovirus (IPV)			1st dose	2nd dose	← 3rd dose →							4th dose	See Notes							
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)						1 or more doses of 2024–2025 vaccine (See Notes)														
Influenza (IIV3, ccIIV3)						1 or 2 doses annually								or 1 dose annually						
Influenza (LAIV3)														1 or 2 doses annually		or 1 dose annually				
Measles, mumps, rubella (MMR)						See Notes	← 1st dose →					2nd dose								
Varicella (VAR)							← 1st dose →					2nd dose								
Hepatitis A (HepA)						See Notes	2-dose series (See Notes)													
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)														1 dose						
Human papillomavirus (HPV)															See Notes					
Meningococcal (MenACWY-CRM ≥2 mos, MenACWY-TT ≥2years)		See Notes											1st dose		2nd dose					
Meningococcal B (MenB-4C, MenB-FHbp)															See Notes					
Respiratory syncytial virus vaccine (RSV [Abrysvo])															Seasonal administration during pregnancy (See Notes)					
Dengue (DEN4CYD: 9–16 yrs)															Seropositive in endemic dengue areas (See Notes)					
Mpox																				

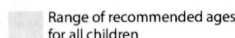
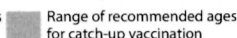
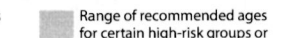
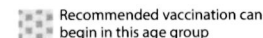
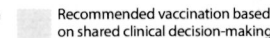
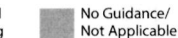
 Range of recommended ages for all children
  Range of recommended ages for catch-up vaccination
  Range of recommended ages for certain high-risk groups or populations
  Recommended vaccination can begin in this age group
  Recommended vaccination based on shared clinical decision-making
  No Guidance/Not Applicable

EXHIBIT 3

60-Day Demand to Secretary Kennedy

LAW OFFICES OF
RAY L. FLORES II

TORREY RESERVE NORTH COURT
11622 EL CAMINO REAL
SUITE 100
SAN DIEGO, CALIFORNIA 92130

TELEPHONE: (858) 367-0397

FACSIMILE: (888) 336-4037

**NOTICE OF INTENT TO COMMENCE CIVIL ACTION AGAINST HEALTH
AND HUMAN SERVICES SECRETARY ROBERT F. KENNEDY, JR., FOR
VIOLATIONS OF THE VACCINE INJURY COMPENSATION PROGRAM**

March 15, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Secretary Kennedy,

In my capacity as citizen, a family man, and a counselor at law, I am informing you that your office is withholding critical information and is not fulfilling its duties, as mandated by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 et seq.) This continuing failure keeps me from being able to make informed decisions that would support my family's health.

As you are aware, for over 35 years the Secretary has had an ongoing duty, that is a 'Mandate for safer childhood vaccines' § 300aa-27(a). The Secretary has failed to:

Establish a task force § 300aa-27(b)

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

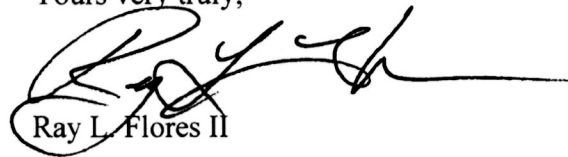
Report § 300aa-27(c)

(c) Within 2 years after the effective date of this part [effective Dec. 22, 1987], and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the

Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

Please also be advised that if a task force is not established, and a Senate Report is not prepared and transmitted within the statutorily-required 60-day rectification period, I intend to file civil suit in a United States District Court against you in your official capacity for your violations of the National Vaccine Injury Compensation Program as provided by 42 USC § 300aa-31. 'Citizens Actions.'

Yours very truly,



Ray L. Flores II

EXHIBIT 4

U.S.P.S. Tracking Confirmation



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1101 COLORADO ST
BOULDER CITY, NV 89005-9998
(800)275-8777

03/15/2025 12:58 PM

Product	Qty	Unit Price	Price
Priority Mail® Window FR Env Washington, DC 20201 Flat Rate Expected Delivery Date Tue 03/18/2025 Tracking #: 9505 5100 5764 5074 9079 82 Insurance Up to \$100.00 included	1		\$10.10 \$0.00
Total			\$10.10

Grand Total: \$10.10

Debit Card Remit \$10.10
Card Name: VISA
Account #: XXXXXXXXXXXX7128
Approval #: 003302
Transaction #: 929
Receipt #: 041771
Debit Card Purchase: \$10.10
AID: A0000000980840 Chip
AL: US DEBIT
PIN: Verified

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WASHINGTON, DC 20201

March 17, 2025, 11:39 am

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PAGE 3 of 3

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FAQs

EXHIBIT 5

**Complaint for Declaratory and Injunctive Relief
(Case 1:18-CV-03215-JMF)**

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Defendant.

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

Plaintiff as for its Complaint against the above-captioned Defendant alleges as follows:

INTRODUCTION

1. The National Childhood Vaccine Injury Act of 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34, granted economic immunity to pharmaceutical companies for the injuries caused by their vaccines. The responsibility for vaccine safety was therefore placed in the hands of the United States Department of Health and Human Services (“HHS”) pursuant to 42 U.S.C. § 300aa-27(a) which provided, *inter alia*, that the Secretary of HHS “shall ... make or assure improvements in ... the licensing, manufacturing, ... adverse reaction reporting, ... and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.”

2. To track HHS’s fulfillment of these vaccine safety obligations, 42 U.S.C. Section 300aa-27(c) provided that, “Within 2 years after December 22, 1987, and periodically thereafter, the Secretary [of HHS] shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.”

3. On May 31, 2017, Robert F. Kennedy, Jr. and Plaintiff's founder, Del Bigtree, along with a handful of other individuals, had a two-hour meeting regarding vaccine safety with the Counselor to the Secretary of HHS, the Director of the National Institutes of Health ("NIH"), Principal Deputy Director of the NIH, and the Directors from various institutes at the NIH. During that meeting, Plaintiff and Robert F. Kennedy, Jr. became concerned that HHS was not faithfully fulfilling its obligations under 42 U.S.C. § 300aa-27(a). Plaintiff therefore decided to submit a request, pursuant to the Freedom of Information Act (5 U.S.C. § 552) ("**FOIA**"), to obtain copies of the reports the Secretary of HHS submitted to Congress pursuant to 42 U.S.C. § 300aa-27(c) which should detail the actions taken by HHS pursuant to 42 U.S.C. § 300aa-27(a) to improve vaccine safety.

4. On August 25, 2017, Plaintiff submitted a FOIA request to the HHS for: "Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c)." (the "**FOIA Request**"). HHS failed to timely respond to the FOIA Request. Plaintiff brings this action to challenge HHS's failure to respond and provide copies of its reports to Congress pursuant to this section, copies of which HHS should have readily accessible.

PARTIES

5. Plaintiff Informed Consent Action Network (“**Plaintiff**” or “**ICAN**”) is a not-for-profit organization with an office located at 140 Broadway, 46th Floor, New York, New York 10005.

6. Defendant the United States Department of Health and Human Services (“**Defendant**” or “**HHS**”) is a department within the Executive Branch of the United States Government and is an agency within the meaning of 5 U.S.C. §552(f).

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(a).

FACTS

I. Background

8. By 1986, the “litigation costs associated with claims of damage from vaccines had forced several companies to end their vaccine research and development programs as well as to stop producing already licensed vaccines.” (Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, at 2 (1994).) The remaining pharmaceutical companies producing vaccines threatened to withdraw from the vaccine market.

9. In response, Congress passed the National Childhood Vaccine Injury Act, in 1986, codified at 42 U.S.C. §§ 300aa-1 through 300aa-34 (the “**1986 Act**”), which virtually eliminated economic liability for pharmaceutical companies for injuries caused by their vaccines. 42 U.S.C. § 300aa-11 (“No person may bring a civil action for damages in the amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal

court for damages arising from a vaccine-related injury or death.”); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) (“we hold that the National Childhood Vaccine Injury Act pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects”).

10. By granting immunity from actual or potential liability from injuries caused by vaccines, Congress eliminated the market forces that are generally relied upon to assure the safety of all other products. Recognizing that the 1986 Act eliminated the incentive for vaccine makers to assure the safety of their vaccine products, the 1986 Act explicitly places the responsibility for vaccine safety in the hands of the United States Department of Health and Human Services (“HHS”). 42 U.S.C. §§ 300aa-1 through 300aa-34.

11. To that end, Section 300aa-1, entitled “Establishment,” provides that “The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.”

12. Section 300aa-2, entitled “Program responsibilities,” provides that the National Vaccine Program’s responsibilities shall include, *inter alia*:

- (1) Vaccine research. The Director of the Program shall ... coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to ... prevent adverse reactions to vaccines.
- (2) Vaccine development. The Director of the Program shall ... coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for

International Development to develop the techniques needed to produce safe and effective vaccines.

- (3) Safety and efficacy testing of vaccines. The Director of the Program shall ... coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

* * *

- (7) Evaluating the ... adverse effects of vaccines and immunization activities. The Director of the Program shall ... coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring ... adverse effects of vaccines and immunization activities.

13. Reflecting the importance of HHS's responsibility to assure vaccine safety, Section 300aa-27(a), entitled "Mandate for safer childhood vaccines," puts the following responsibility directly in the hands of the Secretary of HHS:

- (a) In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—
 - (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
 - (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

14. To assist the Secretary of HHS in performing these duties, Section 300aa-27(b) directs the Secretary to establish a task force responsible for making recommendations to the Secretary concerning implementation of the requirements of Section 300aa-27(a). This task force is entitled the “task force on safer childhood vaccines.” (the “**Task Force**” or “**Task Force on Safer Childhood Vaccines**”). 42 U.S.C. § 300aa-27(b). The Director of the NIH is the chair of the Task Force, which by statute also includes the Commissioner of the FDA and the Director of the CDC. *Id.*

15. As provided in Section 300aa-27(b)(3):

In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

16. The Task Force, chaired by the Director of NIH, is therefore statutorily responsible, pursuant to Section 300aa-27(b), to provide the Secretary of HHS with recommendations concerning implementation of the requirements of Section 300aa-27(a).

17. To assure the Secretary of HHS takes action based on the recommendations made by the Task Force and is otherwise fulfilling its important obligations pursuant to Section 300aa-27(a) to assure the safety of the vaccines administered to children in the United States, Section 300aa-27(c) provides that:

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

18. The rapid growth in the number of pediatric vaccines since passage of the 1986 Act has only increased the need for HHS to faithfully fulfill its obligations under 42 U.S.C. § 300aa-1

et seq. to assure the safety of vaccines used in this country. In 1983, the CDC's childhood vaccine schedule included 11 injections of 4 vaccines. (CDC, 1983 Childhood Immunization Schedule available at <https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg>.) As of 2018, the CDC's childhood vaccine schedule had grown to include 56 injections of 30 different vaccines. (CDC, 2018 Childhood Immunization Schedule available at <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>)

19. Robert F. Kennedy, Jr. and Plaintiff's founder, Del Bigtree, along with a few other individuals concerned about vaccine safety, had a two-hour meeting at the NIH in Bethesda, Maryland on May 31, 2017 with the Counselor to the Secretary of HHS, Director of the NIH, the Principal Deputy Director of the NIH, and the Directors from various institutes at the NIH. During that meeting regarding vaccine safety, Plaintiff and Robert F. Kennedy, Jr., became concerned that HHS was not fulfilling its obligations under 42 U.S.C. § 300aa-27(a). Plaintiff therefore decided to submit a FOIA request to obtain copies of the reports the Secretary of HHS was required to submit to Congress pursuant to 42 U.S.C. § 300aa-27(c), copies of which HHS should have readily available.

II. The FOIA Request

20. On August 25, 2017, Plaintiff sent the FOIA Request via email and FedEx to HHS.

21. On November 8, 2017, HHS finally provided an acknowledgement letter for the FOIA Request, which stated in relevant part:

This acknowledges receipt of your August 25, 2017, Freedom of Information Act (FOIA) request, submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division concerning: **"Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate**

by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c) [sic].”.

We received your request on **August 28, 2017**.

We have initiated a search to locate records falling within the scope of your request. If our searching units advise us that you have requested a voluminous amount of records that require extensive search and examination, my staff will contact you shortly to discuss your willingness to modify your request.

The FOIA requires that we respond to your request within 20 working days of its receipt in this office. Please note the following unusual and exceptional circumstances that will impact our response time: (1) we will need to search for and collect records from components and/or field offices external to this office; and (2) because we receive a very heavy volume of FOIA requests, we will process your request in line with our established policy of “first in, first out” case processing. If either of these circumstances prevents our office from responding within the 20 working day timeframe, we will utilize a 10 working day extension to process your request, as permitted pursuant to the FOIA.

(Emphasis in original.)

22. HHS never requested that Plaintiff modify the FOIA Request. HHS also failed to respond within 20 days nor did it seek a 10 day extension thereafter for responding to the FOIA Request. HHS also did not respond to the numerous follow-up inquiries for a status update regarding the FOIA Request, including inquiries sent on January 23, 2018, January 30, 2018, and February 6, 2018.

23. On March 13, 2018, Plaintiff appealed the FOIA Request to Deputy Agency Chief FOIA Officer at HHS and received an acknowledgment of this appeal from HHS which provided, in relevant part: “This is in response to your Freedom of Information Act (FOIA) appeal, dated: **March 13, 2018**, concerning the constructive denial of your initial request, which is assigned case number 2017-01119-FOIA-OS. We received your appeal on **March 13, 2018**.” (emphasis in

original). HHS, however, failed to respond within 20 days nor did it seek an extension of the statutory processing time for this administrative appeal.

Requested Relief

WHEREFORE, Plaintiff prays that this Court:

- a. Provide for expeditious proceedings in this action;
- b. Enter an Order declaring that it was unlawful for the Defendants' to fail to timely either (1) disclose the reports transmitted by HHS to Congress pursuant to 42 U.S.C. § 300aa-27(c), (2) assert an exemption for such reports, or (3) state that no such reports exist;
- c. Enter an Order directing HHS to, within 20 days of issuance of the order, either (1) make available to Plaintiff any and all reports responsive to the FOIA Request; (2) assert a valid exemption listed in 45 CFR §§ 5.31, 5.32 for withholding any such reports; or (3) state that no such reports exist;
- d. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and
- e. Grant such other and further relief as the Court may deem just and proper.

Dated: April 12, 2018

SIRI & GLIMSTAD LLP



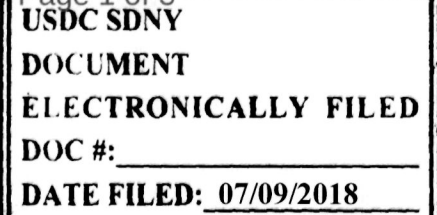
Aaron Siri
200 Park Avenue, 17th Floor
New York, New York 10166
Tel: (212) 532-1091
Co-Counsel for Plaintiff

KENNEDY & MODONNA LLP

Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
Tel: (845) 481-2622
Co-Counsel for Plaintiff

EXHIBIT 6

**Stipulation for Dismissal
(Case 1:18-CV-03215-JMF)**



**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Defendant.

STIPULATION

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows:

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

...

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network (“ICAN”) submitted a Freedom of Information Act request (the “FOIA Request”) to the Department of Health and Human Services (“HHS” or the “Department”), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary (“IOS”) maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

The [Department]’s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

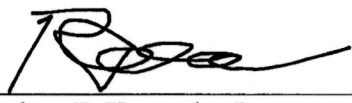
1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff


By:


Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622


Dated: July 6, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By:


ANTHONY J. SUN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
(212) 637-2810
anthony.sun@usdoj.gov

SO ORDERED:


HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

EXHIBIT 7

Letter from HHS dated June 22, 2018 Task Force Disbanded in 1998



DEPARTMENT OF HEALTH & HUMAN SERVICES

PAGE 1 of 2

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email: aaron@sirillp.com

June 22, 2018

Aaron Siri, Esq.
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Re: FOI Case No. 47575, 47756, 47782, 47783, 47881

Dear Mr. Siri:

This is the final response to your Freedom of Information Act (FOIA) requests dated February 15, April 10, April 16, and May 10, 2018, addressed to the FOIA Office, National Institutes of Health, (NIH) and received in this office on those same days. You requested: A copy of all materials associated with the meetings held by the Task Force on Safe Childhood Vaccines, (NIH FOIA Case Number 47575), a copy of the charter for the Task Force for Safer Childhood Vaccines (NIH FOIA Case Number 47756), all agendas, minutes, and transcripts of meetings held by the Task Force on Safer Childhood Vaccines, as well as records sufficient to reflect the dates of these meetings, any and all recommendations made by the Task Force for Safer Childhood Vaccines, and any and all resolutions voted upon by the Task Force on Safer Childhood Vaccines established pursuant to 42 U.S.C. § 300aa-27(b) (NIH FOIA Case Number 47782, 47783, and 47881). All of the aforementioned requests stipulated the same search dates from January 1, 2009 to present.

We queried the files of the NIH Office of the Director, Executive Secretariat, as well as the National Institute of Allergies and Infectious Diseases (NIAID) and no records responsive to your requests, 47575, 47782, 47783, and 47881 were found. Please be advised that the Task Force for Safer Childhood Vaccines was disbanded in 1998.

We have found one record in connection with your request, 47756: The only record that we could find approaching that description is the attached letter establishing the Task Force in 1990. While this date falls out of the timeframe of your request, January 1, 2009 to present, we include this record with this response letter as a courtesy.

Please note that, we are in the process of gathering records responsive to your most recent request, 48013, regarding, "A copy of any and all recommendations made by the Task Force on Safer Childhood Vaccines," from December 22, 1987 to present. We will review those records once that case is next in the queue for review. It is still behind several other cases as of the date of this letter, and all cases will be processed on a first-in first-out basis as mandated by the FOIA.

Page 2 – Mr. Siri (47575, 47756, 47782, 47783, 47881)

If you are not satisfied with the processing and handling of this request you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison

Stephanie Clipper
Public Affairs Specialist
Office of Communications and Public Liaison
Building 1 Room 331
1 Center Drive
Bethesda, MD 20892
301-496-1828 (phone)
nihfoia@mail.nih.gov (email)

OGIS

National Archives and Records Admin.
8601 Adelphi Rd – OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

In certain circumstances provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

If you have any questions about this response please call 301-496-5633.

Sincerely,



Gorka Garcia-Malene
Freedom of Information Officer, NIH

Enclosed: 1 page, PDF